

REMARKS

In the Office Action mailed March 2, 2007, claims 1-5, 8, 10-17, 20, 22-29, 32, 34-36, and 39-40 were pending for consideration, and claims 37 and 38 were withdrawn as a result of a restriction requirement. The Examiner has rejected claims 1-5, 8, 10-17, 20, 22-29, 32, 34-36, and 39-40 under 35 U.S.C. 102(b) as being allegedly anticipated by U.S. Patent No. 5,626,611 (hereinafter “Liu”), or in the alternative under 35 U.S.C. 103(a) as allegedly obvious over Liu. Claims 1, 13, and 25 have been amended. Support for these amendments can be found, *inter alia*, in Examples 4 and 5 of the specification as originally filed. The Applicants stress that these amendments have been made in an effort to advance the prosecution of the present application, and as such, should not be seen as agreement with the positions taken by the Examiner. Additionally, claims 4, 5, 16, 17, 28, and 29 have been canceled. The Applicants reserve the right to pursue any canceled or otherwise withdrawn subject matter in future applications. Additionally, Applicants hereby declare that the amendments made herein do not include any new matter. Claims 1-3, 8, 10-15, 20, 22-27, 32, 34-36, 39, and 40 remain pending for consideration in the present application, and Applicants respectfully submit that these claims are in condition for allowance.

35 U.S.C. § 102(b) Rejections:

The Examiner has rejected claims 1-5, 8, 10-17, 20, 22-29, 32, 34-36, and 39-40 under 35 U.S.C. 102(b) as being allegedly anticipated by Liu. The Applicants respectfully submit that Liu does not teach each and every element of independent claims 1, 13, 25, and 39. Liu teaches co-extruding a core polymer and a shell polymer to form a core/sheath type suture. In one embodiment, the core may be of absorbable polymers, copolymers, or mixtures fabricated from a

laundry list of glycolide, glycolic acid, lactide, lactic acid, caprolactone, dioxanone, trimethylene carbonate, and dimethyl trimethylene carbonate. The shell may be of bioabsorbable polymers made from a laundry list of glycolide, glycolic acid, lactide, lactic acid, caprolactone, dioxanone, trimethylene carbonate, and dimethyl trimethylene carbonate. (col. 3, line 38 to col. 4, line 20).

The amended independent claims of the present application contain limitations to, *inter alia*, a monofilament suture prepared by co-extruding a first absorbable polymer and a second absorbable polymer having a Young's modulus lower than the Young's modulus of the first polymer, wherein the first polymer surrounds the second polymer such that said suture has improved knot security and flexibility, and wherein the Young's modulus of the first polymer and the second polymer is 3.0 GPa or less, and wherein the difference of the Young's modulus between the first polymer and the second polymer is 0.3 GPa or more, and wherein the second polymer a copolymer comprising dioxanone, trimethylene carbonate, and caprolactone, and where the first polymer is a homopolymer or a copolymer synthesized from dioxanone monomers.

The Applicants respectfully submit that the Liu reference does not teach or suggest each of these limitations. The laundry lists of Liu contain the same polymers for the core as for the shell, and there is no teaching found therein that a combination of these polymers be arranged such that the resulting monofilament structure has a core and a shell having a Young's Modulus of 3.0 GPa or less, where the core has a Young's Modulus that is lower than the Young's Modulus of the shell. The embodiments described in col. 3 of Liu, include either a polycaprolactone shell and a polydioxanone core (Young's Modulus of 0.7 and 1.3 respectively) or a polydioxanone shell and a polyglycolide core (Young's Modulus of 1.3 and 7.0 respectively). Both of these embodiments have core polymers with a Young's Modulus that is

greater than the shell, contrary to the features of the independent claims. Additional embodiments described in col. 4, lines 5-20 contain glycolide polymers having a Young's Modulus of greater than 3.0, as is required by the independent claims. Glycolide homopolymers have a Young's Modulus of about 7.0 and glycolide-lactide copolymers have a Young's Modulus of about 5.8. As such, the Liu reference does not teach or suggest each of the limitations of the independent claims, and therefore would not anticipate these claims under 35 U.S.C. 102(b). Reconsideration is respectfully requested. Additionally, the remaining rejected claims depend from, and are therefore considered to be narrower in scope as compared to, the independent claims. As such, reconsideration of the rejections of these claims is requested as well.

35 U.S.C. § 103(a) Rejections:

The Examiner has also rejected claims 1-5, 8, 10-17, 20, 22-29, 32, 34-36, and 39-40 under 35 U.S.C. 103(a) as being allegedly obvious over Liu. It is the Applicants' assertion that the teachings of Liu alone or as modified as suggested by the Examiner would not render obvious the independent claims of the present application. Although the examples in the laundry lists of Liu include many of the monomers used to construct the core and shell components as described in the independent claims of the present application, these monomers are generally well known for biocompatibility, and as such are commonly used. The nonobvious aspects of the independent claims, however, lies not in the presence of a particular set of polymeric materials but rather in the combination of how these materials are put together. It is these teachings that Liu lacks, and that would not be obvious to one of ordinary skill in the art, as is described below.

The same laundry list of monomers is used by Liu to described polymers for the shell and the core of the resulting structure. As such, the teachings that one of ordinary skill in the art would derive from Liu pertaining to an actual polymeric structure would be obtained from the embodiments exemplified therein, and not from the lists themselves. In other words, these lists teach nothing regarding the construction of a polymeric structure, but merely provide a possible list of materials that does not differ between the core and the shell. As such, it would not have been obvious to one of ordinary skill in the art to make a polymeric structure having a dioxanone first polymer surrounding a second polymer made from a copolymer comprising dioxanone, trimethylene carbonate, and caprolactone, as is required by the independent claims of the present application.

It has been widely recognized that virtually every invention is a combination of elements and that most, if not all, of these will be found somewhere in an examination of the prior art. This reasoning lead the court, in *Connell v. Sears, Roebuck & Co.*, 220 USPQ 193, 199 (Fed. Cir. 1983) to state:

"...it is common to find elements or features somewhere in the prior art. Moreover, most if not all elements perform their ordained and expected function. The test is whether the claimed invention as a whole, in light of all the teachings of the references in their entireties, would have been obvious to one of ordinary skill in the art at the time the invention was made." (underlining added)

In re Sernaker, 217 USPQ 1, 5-6, (Fed. Cir. 1983) states a test to determine whether a rejection of an invention based on a combination of prior art elements is appropriate as follows:

"The lesson of this case appears to be that prior art references in combination do not make an invention obvious unless something in the prior art references would suggest the advantage to be derived from combining their teachings.....The board never showed how the teaching of the prior art could be combined to make the invention."
(underlining added)

Additionally, many of the embodiments of Liu utilize glycolide-containing polymers. As has been described, these polymers have Young's Modulus greater than 3.0, ranging from about 5.8 to about 7.0. In reviewing Liu, one of ordinary skill in the art would have no reason to create a polymeric structure from the laundry lists having a core with a lower Young's Modulus than the shell, where both the shell and core have a Young's Modulus equal to or less than 3.0, particularly when none of the embodiments of Liu fall within these ranges.

Accordingly, Liu alone or as modified does not teach each and every element of the amended independent claims. As such, withdrawal of the rejections of claims 1, 13, 25, and 39 is respectfully requested. Additionally, claims 2, 3, 8, 10-12, 14, 15, 20, 22-24, 26, 27, 32, 34-36, and 40 depend from independent claims 1, 13, 25, and 39, and are considered to be narrower in scope. Withdrawal of the rejections of these claims is also respectfully requested.

CONCLUSION

In view of the foregoing, the Applicants assert that claims 1-3, 8, 10-15, 20, 22-27, 32, 34-36, 39, and 40 of the present application present allowable subject matter and the allowance thereof are requested. If any impediment to the allowance of these claims remains after consideration of the present amendment and above remarks, and such impediment could be removed during a telephone interview, the Examiner is invited to telephone Dr. Todd Alder, or in his absence, Mr. M. Wayne Western, so that such issues may be resolved as expeditiously as possible.

Please charge any additional fees except for Issue Fee or credit any overpayment to Deposit Account No. 20-0100.

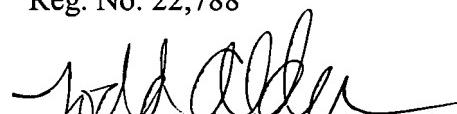
Dated this 1st day of August, 2007.

Respectfully submitted,

THORPE, NORTH & WESTERN, LLP



M. Wayne Western
Reg. No. 22,788



Todd B. Alder Ph.D.
Reg. No. 54,598

8180 South 700 East, Suite 200
Sandy, UT 84070
Telephone: (801) 566-6633
Facsimile: (801) 566-0750

MWW/TBA